

plurality of surface irregularities generally randomly formed therein;

- H1
(Cont.)
- (b) said implantation system having, in combination, an average particle size range and average particle texture such that migration from an injection site is substantially precluded in an autogenous manner and individual particle non-chronic inflammatory scar tissue encapsulation occurs, said particles thereby remaining in situ to form part of said implantation system.

R E M A R K S

In accordance with the above amendments, Claim 99 has been amended; Claims 80-97, 99 and 100 remain under consideration in this application; Claims 1-79, 98 and 101-120, having been canceled. While no claims have been allowed, Claims 81-91, 94-98 and 100 apparently are patentable on the merits but stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1-9 of U.S. Patent No. 5,258,028.

With regard to the obviousness-type double patenting rejection applied to Claims 81-91, 94-98 and 100, applicants stand ready and willing to submit a Terminal Disclaimer commensurate with the expiration date of the aforementioned Patent No. 5,258,028 regarding any claims which issue out of the present application.

Claims 80 and 93 stand rejected under 35 U.S.C. §102(e) as anticipated by or, in the alternative, under 35 U.S.C. §103 as being obvious over Berg et al (U.S. Patent 4,837,285).

Applicants respectfully traverse this rejection. A significant difference between the present claimed invention and the Berg et al. reference lies in the fact that the particles associated with the implantation system of the present invention are not resorbed by the body and themselves remain in situ to form part of the permanent implant. With the requirement in Claim 80, line 4, that the particles be "nonresorbing", the material of Berg et al., while it promotes tissue growth, is itself designed to be resorbed by the body and to disappear within a relatively short time. This is the nature of injected collagen of any form. See, for example, column 3, lines 14-16, which talk about the collagen being "completely resorbable by the patient's body". See also column 5, lines 10-12; column 8, lines 46-48, and 62-63. The resorbable nature of the collagen of the reference in contrast to the injected particulate matter of the present invention which does not resorb or migrate and remains intertwined in the tissue matrix, clearly represents a significant distinction.

The rejection of Claim 99, under 35 U.S.C. §102(b) or 35 U.S.C. §103 with respect to Miyata et al. (U.S. Patent 4,565,580) is also respectfully traversed for substantially the same reasons with respect to the material used. The Miyata et al. particles or beads are made to be used as a beaded substrate for the mass culture of cells and not as a permanent part of an implant

matrix. Regenerated collagen fibrils of Miyata et al. will also be resorbed by the body. Claim 99 has been amended to clarify that the material of the particles are not resorbed.

In view of the above, it is believed that Claims 80, 93 and 99 do patentably distinguish over the applied prior art references and they, together with the remainder of the claims, are patentable on the merits. As stated above, applicants will submit the necessary Terminal Disclaimer with respect to obviousness-type double patenting in due course.

Respectfully submitted,

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CERTIFICATE OF MAILING

I hereby certify that the foregoing Amendment in response to the Official Action of April 25, 1995 in application Serial No. 08/321,571 of inventors, Robert A. Ersek, et al., filed October 10, 1994, for "TEXTURED MICRO IMPLANTS" is being deposited with the United States Postal Service as First Class Mail in an envelope addressed to: Box Non-Fee Amendments, Commissioner of Patents and Trademarks, Washington, D.C. 20231 on July 25, 1995.

